APR 0 2 2013

5 510(k) Summary

As required by section 21 CFR 807.92(c)

Date Prepared: March 15, 2013

510(k) Submitter	Contact for Official Correspondence
B. Braun Interventional Systems Inc. 3100 West Lake Street, Suite 420 Minneapolis, MN 55416	Amber Kingston Director of Marketing and Administration Tel: 610-997-4459; Fax: 612-354-3423 Email: Amber.Kingston@bbraun.com

General Information	
Trade Name	Celsite® Implantable Access Port Systems
Common / Usual Name	Intravascular Infusion Port and Catheter Systems
Classification Name	Subcutaneous, implanted, intravascular infusion port and catheter
Classification Information	This device has been classified by the General Hospital Panel into Class II per 21 CFR 880.5965 (Product Code: LJT)
Predicate Devices	Celsite Implantable Access Port Systems (K061424, K993024, K994111, K962230, K952548, K952435, K945752, K945551)

Device Description

The Celsite® Implantable Access Port Systems (Celsite port systems) are implantable port and catheter systems that allow safe, repeated access to the patient's bloodstream. The port chamber and catheter design can be used for the administration of medication and fluids. The Celsite system consists of an access port with a silicone septum, which is connected to a catheter using a connection ring. The triangular shaped access port has a low profile nose, finger stops on the side of the housing, and a round base. Celsite access ports have suture holes or suture zones to secure placement during implantation.

Celsite family infusion port product lines include: Celsite, Celsite Discreet, and Celsite Concept. Celsite product lines are offered in 'standard' or 'small' sizes.

- *Celsite Access ports* are manufactured with a low-profile design with titanium / polysulphone or titanium / epoxy materials. Catheters are available in either polyurethane or silicone materials. Some Celsite ports are available with pre-connected catheters.
- *Celsite Discreet ports* are manufactured with a low-profile design with a left or right off-set exit cannula that permits a vertical incision and a 90 degree port/exit cannula. Celsite

Discreet ports are manufactured with titanium / epoxy materials. Catheters are available in either polyurethane or silicone materials.

- *Celsite Concept ports* are manufactured with a low-profile, light weight design and have three silicone suture areas, which provide the physician with flexibility in suturing. Celsite Concept ports are manufactured with titanium / polysulphone / silicone materials. Catheters are available in either polyurethane or silicone materials.

Intended Use / Indications

Celsite Access Ports are indicated for patient therapies requiring repeated access to the vascular system.

- Celsite / Celsite Concept Access Ports are indicated for intra-venous administration of drugs for chemotherapy, antibiotics and anti-viral drugs, and for parenteral nutrition, blood sampling or transfusion.
- Celsite Discreet / Celsite Dual Venous / Celsite Brachial / Celsite Babyport / Celsite Babyport S Ports are recommended for use whenever patient therapy requires repeated I.V. Access for injection, drug therapy and/or blood sampling.

Substantial Equivalence Comparison

Intended Use and Principles of Use

The subject and predicate B. Braun Celsite port systems are identical in indications, intended use, and principle of operation. The Celsite port systems are indicated for patient therapies requiring repeated access to the vascular system. Celsite access ports are implantable devices that may be delivered through venous implantation techniques using a percutaneous or surgical approach.

Comparison of Technological / Physical Characteristics

The subject and predicate B. Braun Celsite port system includes an access port with a silicone septum, which is connected to a catheter, and implantation accessories. The port and catheter design, materials, sterile package configuration, sterilization process, and shelf life remain the same as for the currently marketed Celsite ports. The subject and predicate systems differ only in the Winged Surecan needle implantation accessory components that are provided in the shelf package. New Winged Surecan needles differ in purchased state, material formulation, and tubing length when compared to those provided in the currently marketed package.

Summary of Non-Clinical Evaluations

The new Winged Surecan needle versions have been evaluated by the device manufacturer through ISO 14971-compliant risk assessment, design verification, and biocompatibility evaluations. Results of risk assessment review showed no new potential risks were raised due to the new Winged Surecan needle versions. Design verification testing for the new needle versions, which included leakage, visual inspection, manual wing bending, strength test, check for exudation, detachment, and functional tests showed the test articles met acceptance criteria.

Biocompatibility evaluations provide support for the biomaterial safety of the different material formulations used in the new Winged Surecan needle versions.

Substantial Equivalence Conclusion

The Celsite port system has substantially equivalent indications / intended use, principle of operation, and fundamental scientific technology when compared to the currently marketed Celsite predicate port system. The subject and predicate systems are identical, differing only in the Winged Surecan needle implantation accessory components that are provided in the shelf package. New Winged Surecan needles, which differ in purchased state, material formulation, and tubing length, have been evaluated by the device manufacturer through risk assessment, design verification, and biocompatibility evaluations. Results of these evaluations showed no new potential risks were raised due to the new Winged Surecan needle versions; the test articles met the design verification acceptance criteria, thereby demonstrating the mechanical integrity of the device over the labeled shelf life. Biocompatibility evaluations provide support for the biomaterial safety of new Winged Surecan needle versions. The Celsite port systems with the new Winged Surecan needle accessories do not raise new questions of safety or effectiveness when compared to the currently marketed Celsite predicate system, and is, therefore, substantially equivalent.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 2, 2013

Ms. Amber Kingston
Director of Marketing and Administration
B. Braun Interventional Systems, Incorporated
3100 West Lake, Suite 420
MINNEAPOLIS MN 55416

Re: K130576
Trade/Device Name: Celsite® Implantable Access Port Systems
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: February 28, 2013
Received: March 7, 2013

Dear Ms. Kingston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K130576**

Device Name: **Celsite® Implantable Access Port Systems**

Indications for Use:

Celsite Access Ports are indicated for patient therapies requiring repeated access to the vascular system.

- Celsite / Celsite Concept Access Ports are indicated for intra-venous administration of drugs for chemotherapy, antibiotics and anti-viral drugs, and for parenteral nutrition, blood sampling or transfusions.
- Celsite Discreet / Celsite Dual Venous / Celsite Brachial / Celsite Babyport / Celsite Babyport S Ports are recommended for use whenever patient therapy requires repeated I.V. Access for injection, drug therapy and/or blood sampling.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

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510(k) Number: K130576